

REMARKS

This amendment is being filed in response to the Office Action mailed in this application on May 4, 2005. A Petition for Extension of Time (one-month) accompanies this amendment. By this amendment, claim 9 is canceled and replaced by new claim 17, and claims 10-16 are amended. Accordingly, claims 10-17 are pending in this application. Reconsideration of this application is respectfully requested.

First, applicants once again request reconsideration of the restriction requirement. Applicants believe the reason for requiring restriction in this application indicates that there is still a misunderstanding. Specifically, the restriction requirement appears to regard sepsis as systemic sepsis: "Sepsis occurs when toxins build up in the blood or tissues and can cause systemic infections and organ failures." (See the action requiring restriction, page 2, lines 16-17.) Claim 16, on the other hand, is directed to "[a] method of treating *sepsis in wounds...*" (emphasis added). Sepsis in wounds is local infection. Accordingly, applicants submit that the basis for requiring restriction is a misunderstanding, and they request that the requirement be withdrawn.

Turning to the action on the merits, applicants note that claims 9 and 13-15 were rejected under 35 U.S.C. 102(b) as being anticipated by Bentley et al., U.S. 5,128,136 ("Bentley"). Applicants traverse this rejection.

First, applicants have attempted to amend the claims to avoid even the possibility that the claims could be read as asserted in the office action – that the claims read on a composition containing only iodide. As can be seen in new claim 17, from which all the other pending claims depend directly or indirectly, applicants claim an iodine preparation, suitable for use on wounds, comprising an iodide source, and oxidant and a buffer, that *is* combined at the point of use, generates iodine ***at a physiologically acceptable dose and rate, and maintains a pH at between 4.5 and 6 on the wound.***

A feature of the present invention is to create a composition for a wound which delivers a regulated amount of iodine, as antiseptic, to the wound; that amount being high enough to be an effective antiseptic, yet low enough so as not to incur damage or toxicity in the tissue where the composition is applied.

Bentley, in one embodiment, teaches a composition with a pH of 5.5-7.5, for the purpose of applying a pH neutral solution. The instant application uses pH ranges of 4.5-6. Because the scale of pH is a ten-fold increase or decrease in the hydrogen ion concentration, these ranges are considered markedly different by those in the art (not that there is no possibility of overlap). It is

well known that the slightest changes in pH can drastically alter any reaction, especially physiological processes. pH in the present application allows for a controlled release of iodine. Bentley does not teach a controlled release of iodine for treatment and the iodine reactions of Bentley and the instant application cannot be compared due to the highly different pH environments.

Additionally, where Bentley's composition includes iodide and an oxidizing agent, Bentley holds the iodide separate from the oxidizing agent. When they are combined, the pH of the solution is about 3.4. This is "to ensure optimum Iodine release" (Col. 7, line 41). This is another reason why the iodine reactions of Bentley and the instant application cannot be compared as ensuring optimum iodine release is not the goal of the instant application. In fact, the instant application regulates a controlled deposit of iodine to the wound. It cannot be said that Bentley is capable of a controlled deposit of iodine, as the instant application points out that below pH 4.5 the rate of iodide ions being oxidized is too rapid and is likely to induce toxicity (see page 4, lines 12-15). As discussed above, when the iodide-oxidant solution in Bentley is combined with the collagen solution, the pH is neutralized and is not capable of controlled delivery of iodine to the wound.

For all these reasons, applicants request that this rejection be withdrawn.

Finally, claims 9-12 and 15 were rejected under 35 U.S.C. 102(b) as being anticipated by Martindale: The Extra Pharmacopoeia, Thirteenth Edition, 1993 ("Martindale"). Applicants traverse this rejection as well.

As noted above, applicants have attempted to amend the claims to avoid even the possibility that the claims could be read as asserted in the office action – that the claims read on a composition containing only iodide. Clearly the claims require more than solutions of potassium iodide and sodium iodide that are pharmaceutical grade. Accordingly, this rejection is without merit and should be withdrawn.

Applicants request that the Examiner contact the undersigned by telephone, at the number indicated below, in the event that the Examiner is not satisfied with the current claims. Additionally, applicants request reconsideration of the application, withdrawal of the restriction requirement and the rejections, and allowance of the application with claims 10-17.

Respectfully submitted,

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